

16 MAR 2005

40/53496U IFD

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

Abrahamsen, Robert M.
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

13.01.2005

Applicant's or agent's file reference

B1075.7003610000

IMPORTANT NOTIFICATION

International application No.
PCT/US 03/36488

International filing date (day/month/year)
17.11.2003

Priority date (day/month/year)
15.11.2002

Applicant
C.R. BARD, INC. ET AL.

DOCKETED

FEB 3 2005

Initials

Confirmation ☐

Docketing ☒

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Viegas da Cruz, I

Tel. +31 70 340-1923



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference B1075.70036	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US 03/36488	International filing date (<i>day/month/year</i>) 17.11.2003	Priority date (<i>day/month/year</i>) 15.11.2002
International Patent Classification (IPC) or both national classification and IPC A61B18/14		
Applicant C.R. BARD, INC. ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 03.05.2004	Date of completion of this report 13.01.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Mayer-Martenson, E Telephone No. +31 70 340-4401 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT****JC20 Rec'd PCT/PTO 1 6 MAY 2005**

International application No. PCT/US 03/36488

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-4, 6-13 as originally filed
5 received on 15.03.2004 with letter of 15.03.2004

Claims, Numbers

1-35 received on 26.07.2004 with letter of 26.07.2004

Drawings, Sheets

1/4, 3/4, 4/4 as originally filed
2/4 received on 15.03.2004 with letter of 15.03.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/US 03/36488**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 16-35

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 16-35 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-15
	No: Claims	
Inventive step (IS)	Yes: Claims	1-15
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

2. Citations and explanations

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/US 03/36488**

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US 03/36488

Re Item III

Non-establishment of report with regard to novelty, inventive step and industrial applicability

The various definitions of the subject-matter given in the plurality of independent claims, each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as a whole are not clear and concise. The requirements of Article 6 PCT, therefore, are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Article 33.1 PCT should be based.

Therefore, this presentation of a number of independent claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden to others seeking to establish the extent of monopoly requested.

For this reason a full substantive preliminary examination cannot be carried out.

In the following an examination is performed on the first independent claim (claim 1) and its dependent claims (claims 2-15) only.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-B1-6 287 306 (PENDAKANTI RAJESH ET AL) 11 September 2001 (2001-09-11)

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

An apparatus for ablating tissue, comprising:

a shaft (32); and

a tissue ablating electrode comprising a first end portion (36 at 35) and a middle portion (36 at 34) supported by respective lengthwise sections of the shaft;

The subject-matter of claim 1 differs from this known apparatus in that

the total energy emitting surface area of the electrode per unit length of the shaft is greater for the middle portion than for the first end portion of the electrode;

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as facilitating the production of the electrode.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US 03/36488

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

in D1 a configuration of an electrode is shown, which has portions with different resistivities to reduce edge effects on the electrode. This requires a multitude of different materials to construct the apparatus. In claim 1 instead the same effect of reduction of edge effects is achieved by altering the distribution of the energy emitting electrode surface. This facilitates the production of the electrode.

Neither in D1 nor in any other document it is suggested to provide a configuration as described in claim 1 to counteract edge effects on an electrode. Therefore claim 1 is also considered inventive.

Claims 2-15 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

CLAIMS

1. An apparatus for ablating tissue, comprising:
a shaft; and
5 a tissue-ablating electrode comprising a first end portion and a middle portion supported by respective lengthwise sections of the shaft, wherein the total energy-emitting surface area of the electrode per unit length of the shaft is greater for the middle portion of the electrode than for the first end portion of the electrode.
- 10 2. The apparatus of claim 1, wherein the first end portion of the electrode comprises a first section of a coiled conductor, which first section has spirals that are spaced apart from one another.
- 15 3. The apparatus of claim 2, wherein the middle portion of the electrode comprises a second section of the coiled conductor, which second section has spirals that are closer together than the spirals of the first section of the coiled conductor.
- 20 4. The apparatus of claim 3, wherein at least two of the spirals in the second section of the coiled conductor touch each other.
- 25 5. The apparatus of any of claims 1-4, wherein the electrode comprises a coiled conductor having spaces between at least some of its spirals, and a cross-sectional width of the conductor forming the spirals is narrower in the first end portion than in the middle portion.
- 30 6. The apparatus of any of claims 1-5, wherein the electrode comprises at least two separate coiled conductors having interleaved spirals.
7. The apparatus of any of claims 1-6, wherein the electrode comprises a coiled conductor having spaces between adjacent spirals that gradually decrease in size beginning at each end of the electrode and ending in a middle of the electrode.

26-07-2004

Jul 26

15:59

P.07

US0336488

07

26.07.2004

21:58:19

- 15 -

8. The apparatus of claim 1, wherein the electrode comprises a conductor of a generally cylindrical shape that is partially masked with a non-conductive substance at least in the first end portion of the electrode.

5 9. The apparatus of claim 1, wherein the electrode comprises a conductor of a generally cylindrical shape.

10. The apparatus of any of claims 1-9, in combination with an ablation energy generator to energize the electrode with sufficient energy to ablate tissue.

10

11. The apparatus of any of claims 1-10, wherein the shaft comprises a distal end of an elongated catheter.

12. The apparatus of claim 11, wherein the distal end of the elongated
15 catheter is steerable.

13. The apparatus of any of claims 1-12, wherein the electrode is mounted on the shaft such that at least a portion of an end of the electrode is disposed at least partially below an annular surface of the shaft that is adjacent the end of the electrode.

20

14. The apparatus of claim 13, wherein the electrode is mounted on the shaft such that at an upper surface of the end of the electrode is substantially flush with the annular surface of the shaft that is adjacent the end of the electrode.

25 15. The apparatus of any of claims 1-14, wherein the electrode further comprises a second end portion opposite the first end portion, and wherein the total energy-emitting surface area of the electrode per unit length of the shaft is greater for the middle portion of the electrode than for the second end portion of the electrode.

30 16. A apparatus for ablating tissue, comprising:
a shaft; and
a tissue-ablating electrode mounted to the shaft, the electrode comprising at least a first end portion and a middle portion, and having at least one energy emitting area configured in a shape other than a coil, wherein at least the middle portion is configured

- 16 -

and arranged to introduce edge effects in the middle portion such that, when the conductor is energized, the ratio of a first density of ablation energy emitted in a vicinity of the first end portion to a second density of ablation energy emitted in a vicinity of the middle portion is lower than the ratio would be if the electrode were not configured and arranged to introduce such edge effects in the middle portion.

17. The apparatus of claim 16, wherein the electrode comprises a conductor of a generally cylindrical shape that is partially masked with a non-conductive substance at least in the middle portion so as to introduce edge effects in the middle portion.

18. The apparatus of claim 16 or 17, wherein the electrode comprises a conductor of a generally cylindrical shape that has a lower density of energy-emitting surface area in the vicinity of the first end portion than in the vicinity of the middle portion.

19. The apparatus of any of claims 16-18, in combination with an ablation energy generator operatively coupled to the electrode to enable the ablation energy generator to transmit sufficient energy to the electrode to ablate tissue.

20. The apparatus of any of claims 16-19, wherein the shaft comprises a distal end of an elongated catheter.

21. The apparatus of claim 20, wherein the distal end of the elongated catheter is steerable.

22. The apparatus of any of claims 16-21, wherein the electrode is mounted on the shaft such that at least a portion of an end of the electrode is disposed at least partially below an annular surface of the shaft that is adjacent the end of the electrode.

23. The apparatus of claim 22, wherein the electrode is mounted on the shaft such that at an upper surface of the end of the electrode is substantially flush with the annular surface of the shaft that is adjacent the end of the electrode.

26-07-2004

Jul 26

15:59

P.09

US0386488

09 26.07.2004

21:58:58

- 17 -

24. The apparatus of any of claims 16-23, wherein the electrode further comprises a second end portion opposite the first end portion, and wherein at least the middle portion is configured and arranged to introduce edge effects in the middle portion such that, when the conductor is energized, the ratio of a third density of ablation energy emitted in a vicinity of the second end portion to the second density of ablation energy emitted in the vicinity of the middle portion is lower than the ratio would be if the electrode were not configured and arranged to introduce such edge effects in the middle portion.

10 25. A apparatus for ablating tissue, comprising:
a shaft; and
a tissue-ablating electrode mounted on the shaft, the electrode comprising at least two separate coiled conductors having interleaved spirals.

15 26. The apparatus of claim 25, wherein the electrode comprises at least three separate coiled conductors having interleaved spirals.

20 27. The apparatus of claim 25 or 26, in combination with an ablation energy generator operatively coupled to the at least two conductors to enable the ablation energy generator to transmit sufficient energy to the at least two conductors to ablate tissue.

25 28. The combination of claim 27, in further combination with a controller to control transmission of ablation energy from the ablation energy generator to the at least two conductors in a pulsed, sequential fashion.

29. The apparatus of any of claims 25-28, wherein the shaft comprises a distal end of an elongated catheter.

30 30. The apparatus of claim 29, wherein the distal end of the elongated catheter is steerable.

31. The apparatus of any of claims 25-30, wherein the electrode is mounted on the shaft such that at least a portion of an end of the electrode is disposed at least partially below an annular surface of the shaft that is adjacent the end of the electrode.

26.07.2004

Jul 26 .

6:00

P.10

US0336488

010

26.07.2004

21:59:18

- 18 -

32. The apparatus of claim 31, wherein the electrode is mounted on the shaft such that at an upper surface of the end of the electrode is substantially flush with the annular surface of the shaft that is adjacent the end of the electrode.

5

33. An apparatus for ablating tissue, comprising:

a shaft; and

a tissue-ablating electrode comprising a coiled conductor having spaces between at least some of its adjacent spirals, the electrode being mounted on the shaft such that at least a portion of an end of the electrode is disposed at least partially below an annular surface of the shaft that is adjacent the end of the electrode.

10

34. The apparatus of claim 33, wherein the electrode is mounted on the shaft such that at an upper surface of the end of the electrode is substantially flush with the annular surface of the shaft that is adjacent the end of the electrode.

15

35. A apparatus for ablating tissue, comprising:

a shaft; and

a tissue-ablating electrode mounted to the shaft, the electrode comprising an end portion and a middle portion, and having at least one energy-emitting area configured in a shape other than a coil, the electrode further comprising means for introducing edge effects in at least the middle portion.

20